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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF OREGON  
Portland Division**

**Iran Thalassemia Society**, an  
NGO with over 23,000 thalassemia  
member patients; **H.K.**, a five-year-old  
male Iranian child suffering from  
epidermolysis bullosa; **A.M.**, a similarly  
afflicted seven year old female Iranian  
child; **S.N.**, a similarly afflicted ten year  
old male Iranian child; **M.M.**, a similarly  
afflicted thirteen year old female Iranian  
child; **FZ.H.** a similarly afflicted eighteen  
year old female Iranian youth; **F.E.**, a  
similarly afflicted twenty one year old  
female Iranian youth; **No Child Should  
Suffer**, an Oregon domestic nonprofit  
corporation,

Plaintiffs,

vs.

**Office of Foreign Assets Control; Janet  
Yellen**, Secretary of the Treasury, and  
**Andrea Gacki**, Director of the Office of  
Foreign Assets Control,

Defendants.

**Civil #: 22-civ-1195**

**COMPLAINT:**

**VIOLATIONS OF STATUTORY  
PROHIBITIONS OF INTERFERENCE  
WITH DELIVERY OF HUMANITARIAN  
AID**

**ALIEN TORT CLAIMS ACT  
VIOLATION - NEGLIGENCE**

## I. Introduction

1. This is an action encompassing two types of claims, namely:

- (1) Violation of statutory prohibitions on imposing sanctions on humanitarian aid needed in Iran, and
- (2) Violation of the Alien Tort Claims Act of 1789, 28 U.S.C. § 1350.

2. Plaintiffs collectively are thousands of Iranian children suffering from two serious genetic diseases, *epidermolysis bullosa* and *thalassemia*. Those children no longer can obtain critical medical supplies and drugs to treat their conditions.<sup>1</sup> They have lost access to those items because President Donald Trump, on May 8, 2018, announced his intention to withdraw the United States from the “JCPOA”,<sup>2</sup> following which he re-imposed all of the economic trade sanctions on Iran that had been lifted as a part of the 2015 agreement and, in addition, imposed new “maximum pressure” sanctions in an effort to cripple Iran economically to the point where it would agree to a new, “longer and stronger” agreement limiting a broad range of its international activities.<sup>3</sup> Then-Secretary of State Pompeo was quoted as boasting, “These will indeed end up being the strongest sanctions in history when we are complete.”

3. “Sanction” refers to commercial and financial penalties that the defendant Office of Foreign Assets Control (“OFAC”) applies in countries, in this case Iran, against a targeted group or individual. The individuals and entities that OFAC targets and blocks are prohibited from participating in the dollar-denominated U.S. economic system. Those

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<sup>1</sup> There are hundreds, perhaps thousands, of other children in Iran who are also suffering similarly from other maladies but who are not included within the scope of this complaint.

<sup>2</sup> “JCPOA” is an acronym for the Joint Comprehensive Plan of Action, a 2015 multiparty agreement as described further *infra*.

<sup>3</sup> <https://www.bbc.world-us-canada-44200621>.

whom OFAC targets or blocks are referred to as “Specially Designated Nationals”, or “SDNs.” OFAC is empowered to impose severe penalties on any third party, including foreign banks, that engage in commercial transactions with a SDN. Such penalties can include barring the foreign bank from future access to the dollar-denominated U.S. economic system.

4. President Trump’s new, post-JCPOA sanctions ultimately targeted virtually the entire Iranian banking sector. This meant that other participants in the dollar-denominated U.S. economic system, primarily foreign banks, were prohibited from dealing with the sanctioned Iranian banks, which in turn meant that the Iranian economy became isolated from the dollar-denominated U.S. economic system. As a consequence, foreign banks ceased dealing with their blocked Iranian counterparts, isolating Iran from major portions of international commerce.

5. A foreign bank prohibited from access to the dollar-denominated U.S. economic system would in most cases perish economically. The net result of President Trump’s sanctioning the entire Iranian banking system was to make commercial transactions with Iranian businesses, including those that wish to purchase humanitarian aid, extremely difficult if not impossible

6. The new sanctions crippled the Iranian economy, and the negative effects are still being felt. Ultimately, however, President Trump’s campaign failed. Iran refused to renegotiate the JCPOA and, after a year of waiting for the European parties to the JCPOA to take steps to lessen the impact of the new maximum pressure sanctions, Iran began relaxing its compliance with the terms of the JCPOA. Today, as a result, Iran is said to be at the threshold of creating a nuclear weapon.

7. As noted above, the result of the new sanctions was for Western business interests that previously had been willing to deal with Iranian purchasers to terminate

those prior arrangements and isolate Iranian purchasers, including Iranian purchasers of humanitarian aid such as medical supplies and drugs of the type afflicted plaintiffs herein require for life support.

8. As a direct and immediate consequence of the maximum pressure sanctions, the afflicted plaintiffs today are suffering and many are dying. The two diseases afflicting plaintiff children in this litigation are thalassemia (the major form of the disease is known in the West as “*Cooley’s Anemia*”) and epidermolysis bullosa (“EB,” often referred to as “the butterfly disease” because the skin of those afflicted is as fragile as butterfly wings). The annual mortality rate for afflicted Iranians suffering from thalassemia has jumped from 30-40 deaths per year to 150 deaths per year since imposition of the maximum pressure sanctions. This means that approximately every three days another death results from the ongoing maximum pressure sanctions.

9. Thalassemia is a genetic blood disorder that is treated by blood transfusions. Blood transfusions, however, cause excess iron to be concentrated in the patient’s blood which, unless treated, can cause iron toxicity, compromise vital organs (heart, liver, spleen, endocrine system), and ultimately lead to death. The preferred treatment for excess iron is Desferal<sup>®</sup> (deferoxamine mesylate), a drug manufactured by Novartis<sup>4</sup> that is generally available globally but, since imposition of the maximum pressure sanctions, is no longer generally available in Iran. “Desfonac” is the Iranian version of an iron chelating drug that is prescribed in the absence of Desferal<sup>®</sup>, but Desfonac is not as effective as Desferal<sup>®</sup> and causes a number of debilitating side effects. Approximately 617 Iranian thalassemia sufferers have died since May 2018 as a direct and immediate consequence of the unavailability of Desferal<sup>®</sup>, and experts predict that the average life expectancy of Iranian thalassemia patients will be reduced by ten

years so long as that drug is not available. On the other hand, should Desferal<sup>®</sup> become available generally in Iran today, most of those who are now in decline can be expected to recover fully.

10. Epidermolysis bullosa is a genetic skin disorder that causes the skin to become very fragile to the point that the slightest friction can cause blistering and open sores. The blistering and open sores of children suffering from epidermolysis bullosa is best treated by wound dressings (primarily Mepilex<sup>®</sup>), which is manufactured and available only from Mölnlycke Health Care A.B. of Gothenburg, Sweden. Failure to treat the blistering and open sores with Mölnlycke special dressings can result in excruciating pain and lead to a deterioration in general health, possibly leading to the death of the afflicted child. There are over 500 registered epidermolysis bullosa patients in Iran.

11. The new unilateral maximum pressure sanctions caused foreign intermediary banks and financial institutions to be reluctant to engage in transactions with Iranian purchasers because of the fear that defendant OFAC will impose secondary sanctions upon them. This fear is due in large part because of the uncertain scope and complexity of the maximum pressure sanctions. As a result, the required life-saving treatments and drugs are no longer generally available in Iran.

12. On October 25, 2019, OFAC issued a release stating that it would establish a process whereby foreign banks could participate in the delivery of humanitarian aid to Iran without fear of OFAC imposing secondary sanctions on them and their client(s) (the “Release”). The Release was titled, “Financial Channels to Facilitate Humanitarian Trade with Iran and Related Due Diligence and Reporting Expectations.”<sup>5</sup> In order to enjoy this “safe harbor,” OFAC stated that foreign banks “must commit to conducting

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<sup>4</sup> Novartis is a Swiss-U.S. pharmaceutical company.

<sup>5</sup> Available at [https://home.treasury.gov/system/files/126/iran\\_humanitarian\\_20191025.pdf](https://home.treasury.gov/system/files/126/iran_humanitarian_20191025.pdf).

enhanced due diligence to mitigate the higher risks associated with transactions involving Iran . . .” That commitment anticipated that the foreign banks would “provide to Treasury robust information on the use of this mechanism on a monthly basis.” The Release continues by noting that foreign banks “will be expected to collect, maintain, and report to Treasury, with appropriate disclosure and use restrictions, a great deal of information on a monthly basis.” The following two pages of the Release is a list of examples of the types of detailed information that the participating foreign banks will be expected to provide to Treasury on a monthly basis. In sum, the Release proposed to foreign banks that they might enjoy a safe harbor from secondary sanctions resulting from providing humanitarian aid but only if they agreed to actively seek and turn over to OFAC intelligence information regarding Iranian customers of humanitarian aid.

13. None of the foreign banks that earlier had participated in the sale and delivery of Mepilex<sup>®</sup> and Desferal<sup>®</sup> elected to participate in OFAC’s new scheme. On information and belief, no other foreign banks located in Sweden or in Switzerland participated in deliveries of humanitarian aid into Iran by use of the vehicle described in the preceding paragraph.

14. Since his inauguration over 18 months ago, President Biden has not reduced or eliminated any of the maximum pressure sanctions; indeed, he has added to those sanctions.

## II. Summary of Plaintiffs' Claims

15. Plaintiff's first claim is that the maximum pressure sanctions violate a number of Congressional prohibitions on the imposition of economic sanctions on the delivery of humanitarian aid to Iran. In virtually all statutes that empower the president to impose economic sanctions there is a prohibition against sanctioning humanitarian aid, usually described as agricultural products and medical devices and goods.<sup>6</sup> The new sanctions violate three major statutory provisions: (1) 50 U.S.C. § 1702(b)(2) of the International Emergency Economic Powers Act ("IEEPA"), which provides in part that the President, subject to qualifications not here germane, may not "regulate or prohibit, directly or indirectly" the provision of humanitarian "medicine, intended to be used to relieve human suffering," (2) 22 U.S.C. § 8515a, "Imposition of sanctions with respect to the financial sector of Iran," which provides in part, "The President may not impose sanctions under paragraph 1 [empowering issuance of sanctions] with respect to any person for conducting or facilitating a transaction for the sale of agricultural commodities, food, medicine, or medical devices to Iran," and (3) 22 U.S.C. § 7202(a) of the Trade Sanctions Reform and Export Enhancement Act, which provides:

**(a) New sanctions**

Except as provided in sections 7203 and 7204 of this title and notwithstanding any other provision of law, the President may not impose a unilateral agricultural sanction or unilateral medical sanction against a foreign country or foreign entity, unless—

- (1) not later than 60 days before the sanction is proposed to be imposed, the President submits a report to Congress that—
  - (A) describes the activity proposed to be prohibited, restricted, or conditioned; and
  - (B) describes the actions by the foreign country or foreign entity that

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<sup>6</sup> See, e.g., 22 U.S.C. § 8805(a)(2), "The President may not impose sanctions . . . [on] a transaction for the sale of agricultural commodities, food, medicine, or medical devices to Iran or for the provision of humanitarian assistance to the people of Iran." (Addressing underwriting, insurance, or reinsurance activities.)

- justify the sanction; and  
(2) there is enacted into law a joint resolution stating the approval of Congress for the report submitted under paragraph (1).

16. Plaintiffs' second claim is that "the law of nations" (*i.e.*, customary international law) binding on the United States imposes a duty of care upon the Office of Foreign Assets Control ("OFAC"), an Office of the U.S. Department of the Treasury. The specific duty is that OFAC must protect plaintiff children's health and lives from unnecessary deterioration and death. That duty arises under the requirements set forth in the United Nations Convention on the Rights of the Child ("UNCRC"), which convention has been agreed to by every country in the world and ratified by every country in the world except the United States (the Convention has yet to be submitted to the United States Senate for ratification). Plaintiffs allege that OFAC, which is responsible for drafting Iran economic sanctions, negligently violated its duty and that OFAC's breach of its duty is cognizable under the Alien Tort Claims Act, 28 U.S.C. § 1350, which provides: "The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."

### **III. Parties**

#### **Plaintiffs**

##### **Thalassemia Plaintiffs**

17. Iranian children suffering from thalassemia are represented by Iran Thalassemia Association, an Iranian non-governmental organization formed in 1989 by a number of parents with children suffering from thalassemia major and physicians involved in the treatment of those patients. The Secretary of the Association is Younos



Arab, who like all other members of the Society, was born with thalassemia. The imposition of maximum pressure sanctions and the consequent elimination of suitable iron-chelating drugs have diverted the Association's resources to deal with the lack of suitable medicine and have greatly frustrated the Association's mission.<sup>7</sup>

*Epidermolysis Bullosa Plaintiffs*<sup>8</sup>

18. Iranian plaintiffs suffering from epidermolysis bullosa are **H.K.**, a five-year-old male; **A.M.**, a seven-year-old female; **S.N.**, a ten-year-old male; **M.M.**, a thirteen-year-old female; **FZ.H.** an eighteen-year-old female, and **F.E.**, a twenty-one-year old female. None of the EB plaintiffs has been able to obtain adequate quantities of the required specialized Mepilex<sup>®</sup> dressing since President Trump imposed his maximum pressure sanctions in 2018.

*No Child Should Suffer, an Oregon Domestic Nonprofit Corporation*

19. Plaintiff **No Child Should Suffer** is an Oregon domestic nonprofit corporation formed for the purpose of supporting Iranian children suffering as a result of OFAC's maximum pressure sanctions.

*Defendants*

20. Defendant **Office of Foreign Assets Control ("OFAC")** is an office of the Department of the Treasury of the United States of America that is responsible for drafting, implementing, and enforcing economic sanctions on Iran.

21. Defendant **Janet Yellen** is Secretary of the Treasury of the United States of America. Ms. Yellen is sued in her official capacity only.

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<sup>7</sup> More information about the Association is available at <http://thalassaemia.ir/en/index.cfm>.

<sup>8</sup> Plaintiff EB patients are designated by initials only because of privacy concerns. Their treating physician, Mohammad M. Parvizi, M.D., Ph.D., has been authorized to speak on their behalf in this litigation. Dr. Parvizi is the head of the Molecular Dermatology Research Center at Shiraz University of Medical Sciences in Shiraz, Iran.

22. Defendant **Andrea Gacki** is the Director of OFAC. Ms. Gacki is sued in her official capacity only.

#### **IV. Jurisdiction and Venue**

23. Jurisdiction is based on the Alien Tort Claim Act, 28 U.S.C. § 1350 (“ATCA”),<sup>7</sup> Section 702 of the Administrative Procedure Act, 5 U.S.C. § 702 (review of agency decisions), 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1337 (Commerce), 28 U.S.C. § 1361 (action to compel officer to perform a duty owed to plaintiff), 28 U.S.C. § 1651 (All Writs statute), and 28 U.S.C. § 2201 (declaratory judgments).

24. Under 28 U.S.C. § 1301(e), venue is proper in the District of Oregon because it is the location of plaintiff No Child Should Suffer.

#### **V. Facts**

##### Genesis of Iran Sanctions

25. On August 19, 1953, the United States and Britain planned and participated in a *coup d’état* in Iran that overthrew its democratically elected Prime Minister Mohammad Mossadeq and installed in his place the Shah, Mohammad Reza Pahlavi, as the authoritarian ruler of the country. The coup was engineered because Prime Minister Mossadeq was attempting to assert control over Iranian oil fields then controlled by a predecessor of British Petroleum.

26. Upon the overthrow of Prime Minister Mossadeq, Shah Mohammad Reza Pahlavi abolished the democratic system in Iran and became the absolute ruler with the full support and tutelage of the United States. The Shah’s regime was perceived by many as oppressive, brutal, lavish, and corrupt, and over the years these circumstances led to open civil unrest. In October 1977 that unrest escalated until the Shah, who was then suffering from lymphoma, left the country to seek medical treatment in Egypt.

27. Before his departure, the Shah appointed a caretaker government. In January 1979 that government invited a longtime opponent of the Shah, Ayatollah Ruhollah Khomeini, to return from exile in France to Iran. On February 11, 1979, following the arrival of Ayatollah Khomeini, the caretaker government collapsed. In April 1979 a national referendum was held that abolished the monarchy and in its place established the Islamic Republic of Iran, a theocracy. The theocracy rules Iran today.

28. The deposed Shah, who had become a pariah in Iran, continued to seek treatment for his lymphoma and, in late October 1979, the United States admitted the ailing Shah into the country for medical treatment. News of the admission of the Shah into the United States led to widespread, virulent anti-American demonstrations in Iran, and ultimately in November 1979 radical students in Tehran invaded the American embassy and took its staff as hostages. In response to the hostage crisis, the United States first imposed economic sanctions on Iran.

29. United States economic sanctions on Iran are drafted, adopted, administered, and enforced by defendant OFAC. Under the present sanctions regime, there are two types of sanctions, “primary” sanctions and “secondary” sanctions.

30. Primary sanctions impose prohibitions on “U.S. persons” - persons over which the United States has immediate physical jurisdiction. In the context of Iran sanctions, U.S. persons can be prosecuted civilly and criminally if they violate any prohibitions against economic conduct contained in the Iran Sanctions Act as revised.

31. OFAC can impose secondary sanctions on non-U.S. persons who deal economically with Iranian entities that OFAC has designated as SDNs. The consequences of violating secondary sanctions involve, *inter alia*, potentially hefty financial penalties and complete exclusion from the U.S. dollar-denominated economic

system. In many cases the imposition of the latter sanction would, because of the predominance of the U.S. dollar as the primary international exchange currency, in effect be an economic death sentence to a foreign commercial or banking enterprise.

32. Over the years following the Islamic Revolution, concern grew regarding Iran's intention and ability to develop nuclear weapons. OFAC's initial 1979 Iran sanctions were modified many times in the 35 years up to 2015. In that year, six countries (China, France, Germany, Russia, the United Kingdom, and the United States), along with the European Union, reached an agreement with Iran; that agreement was the JCPOA. The purpose of the JCPOA was to ensure that Iran's nuclear program be exclusively peaceful. In return for Iran agreeing to significant, enforceable limitations on its nuclear activities, the other parties agreed to reduce and limit the multilateral economic sanctions then being imposed on Iran.

33. Iran complied fully and completely with all of the terms of the JCPOA. President Trump, however, during his 2016 campaign stated that he was not happy with the agreement, and that he could and would force Iran to agree to a "better deal." Once elected, on May 8, 2018, the President announced the United States' withdrawal from the JCPOA. As a part of the withdrawal, President Trump announced a new policy of imposing unilaterally "maximum pressure" sanctions on Iran in order to convince Iran to renegotiate the JCPOA with terms more to President Trump's liking. The scope of the maximum pressure sanctions are set forth more fully in the following paragraph. All of these actions were accomplished pursuant to Executive Orders; Congressional consent was neither requested nor received for any of them. The other members of the JCPOA

uniformly opposed President Trump's actions and in several instances attempted to thwart the impact of the new unilateral actions on Iran.

34. A brief outline of the timing of maximum pressure sanctions follows.

- In August 2018 President Trump formally reimposed economic sanctions on Iran that had been withdrawn or waived pursuant to the terms of the JCPOA. The effect of this action was to limit Iran's access to financial markets by adding a number of Iranian institutions to the SDN list.
- In November 2018 OFAC added an additional 37 Iranian governmental and privately owned banks to the list of SDNs. Consequently, a number of business enterprises that previously had provided humanitarian goods to Iran ceased doing so out of fear of possible imposition of secondary sanctions on them because of such transactions.
- On October 25, 2019, OFAC and the Department of State issued a Release titled, "Financial Channels to Facilitate Humanitarian Trade with Iran and Related Due Diligence and Reporting Expectations." That Release announced that, in the case of humanitarian transfers to Iran, henceforth the only avenue that foreign governments or financial institutions could rely on to avoid secondary sanctions would be compliance with a new set of OFAC regulatory requirements involving the gathering of intelligence information for OFAC. The Release states:  
  

[T]his framework will enable foreign governments and foreign financial institutions to seek written confirmation from Treasury that the proposed financial channel will not be exposed to U.S. sanctions in exchange for foreign governments and financial institutions committing to provide to Treasury robust information on the use of this mechanism on a monthly basis.<sup>9</sup>
- On October 8, 2020, OFAC designated 18 additional private banks, which resulted in virtually all Iranian banking concerns being designated.<sup>10</sup>

As a result of the new restrictions, Iranian companies and hospitals have been severely restricted in their ability to purchase previously available essential medicines and

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<sup>9</sup> *Financial Channels to Facilitate Humanitarian Trade with Iran and Related Due Diligence and Reporting Expectations* (October 25, 2019), available at [https://home.treasury.gov/system/files/126/iran\\_humanitarian\\_20191025.pdf](https://home.treasury.gov/system/files/126/iran_humanitarian_20191025.pdf).

<sup>10</sup> The sense of the Trump Administration's enthusiasm for punishing Iran can be viewed in the OFAC November 5, 2018, press release detailing the reimposition of old sanctions and imposition of new ones. See <https://home.treasury.gov/news/press-releases/sm541>.

medical equipment from outside Iran that Iranian patients had come to rely upon for their medical care and well-being.

35. The Biden Administration, elected in November 2020, has not abandoned the Trump Administration's punitive unilateral maximum pressure sanctions on Iran; in fact, the Biden Administration has kept President Trump's sanctions in place and added to them.

36. The present government of Iran is headed by conservative President Ebrahim Raisi, who was elected in June 2021 and took office in August 2021. President Raisi has implemented a fundamental, long-term shift in the strategic position of Iran in the world. Beginning with his administration, Iran began to "look East" by withdrawing from western economic and political relations and associating the country more closely with its immediate and regional neighbors as well as China and, more recently, Russia. These actions are intended, *inter alia*, to reduce if not eliminate the potential future impact of unilateral economic sanctions the United States might impose on Iran and its citizens.

37. In summary, President Trump's unilateral reimposition of sanctions on Iran, along with the added, new maximum pressure sanctions following the United States' unilateral withdrawal from the JCPOA, crippled Iran's ability to secure the continued importation of life-saving humanitarian goods such as medicines and medical devices and equipment. These new, unilateral maximum pressure sanctions also sent a frightening message to those who previously had been willing to provide humanitarian goods and assistance to Iran: The United States, which has enormous unilateral power over the world's dollar-denominated economy, is extremely volatile

politically and, above all, unpredictable. Consequently, a large number of business enterprises that previously had provided humanitarian goods to Iran ceased doing so because of fear of possible imposition of secondary sanctions on them.

Maximum Pressure Sanctions' Impact on Thalassemia Plaintiffs

38. There are approximately 23,000 cases of “thalassemia major” patients in Iran, approximately 6000 of whom are under age 18 and approximately 4000 of whom are under 12. The most common type of thalassemia in Iran is beta-thalassemia, which, depending on its genetic mutation, causes a wide range of clinical symptoms. Those symptoms can include enlarged liver, bone disorders, lack of adequate growth, iron overload in sensitive organs, cardiac arrhythmia, diabetes, problems with coagulation, osteoporosis, hepatitis, and severe and fatal anemias.

39. In order to prevent the complications specified in the preceding paragraph, it is necessary to use iron-chelating drugs to reduce toxic concentrations of iron in the blood. There are three main drugs that have proven successful in reducing those concentrations, primarily Desferal<sup>®</sup>(deferioxamine), but also including Jadenu<sup>®</sup>(deferasirox), and Adakveo<sup>®</sup>(crizanlizumab-tmca). All of these life-saving drugs are manufactured by Novartis, a Swiss-American multinational pharmaceutical corporation based in Basel, Switzerland and Cambridge, Massachusetts.

40. Access to these life-saving Novartis drugs was terminated in late 2020, when President Trump imposed sanctions on an additional 18 Iranian banks, which led to the pharmaceutical companies' financial institutions becoming unwilling to engage in any transaction with designated Iranian banks. The autumn 2020 sanctions raised other impediments to such transactions by foreign exchange and banking service

companies as well as by export, transportation, and insurance companies. As plaintiff Iran Thalassemia Society stated in a November 2019 submission to the United Nations' Human Rights Council,

Since the [Iranian] banking system went under sanctions, no import company or distributor could work in Iran anymore and access to medicine was seriously limited. In addition, the psychological back lash of sanctioning Iran has made the European pharmaceutical companies refrain from selling medicine and medical equipment's [sic.] to Iranians.<sup>11</sup>

41. The inability to obtain the Novartis drugs has increased the number and magnitude of injuries suffered by Iranian plaintiff thalassemia patients to the point that over 600 of such patients have died unnecessarily since the imposition of President Trump's unilateral sanctions. The consequence of the inability to obtain suitable iron-chelating drugs to treat the patients' iron toxicity has been and will continue to be organ failure and early death.

Sanctions' Impact on Epidermolysis Bullosa Plaintiffs

42. For Iranian children suffering from epidermolysis bullosa, an important, primary source of humanitarian dressings is Mölnlycke Health Care AB of Gothenburg, Sweden. Mölnlycke is known internationally for its specialized wound dressings for children suffering from painful blisters caused by EB. The dressings greatly reduce the pain associated with treating the blisters caused by EB.

43. Mölnlycke operates in over 100 countries. Prior to President Trump's maximum pressure sanctions, Iranian children suffering from EB were able access those unique wound dressings, specifically including Mepilex<sup>®</sup>. Plaintiffs HK, AM, SN,

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<sup>11</sup> Iran Thalassemia Society submission to United Human Rights Council (November 2019), *available at* <https://uprdoc.ohchr.org/uprweb/downloadfile.aspx?filename=6675&file=EnglishTranslation>.



and MM are among the over 500 children in Iran who suffer from EB.

44. Because of President Trump's maximum pressure sanctions, Mölnlycke Health Care has refused to provide Mepilex® and other such dressings to Iranian children. A letter postmarked March 18, 2020, signed by Kristin Hedlund, Executive Vice President - Legal and General Counsel, addressed to EB Home, states,

Unfortunately due to the US Economic sanctions in force Mölnlycke Healthcare have decided not to conduct any business in relation to Iran for the time being. This also applies to business conducted under any form of exemption to the US Economic sanctions. We are constantly monitoring the situation and hope to be able to support your need in the near future.<sup>12</sup>

This letter was sent less than five months following OFAC's new requirements for foreign governments and financial institutions wishing a safe harbor from secondary sanctions. It illustrates, inter alia, the strong impact that the implicit threat of secondary sanctions had upon providers of humanitarian aid needed by Iran.

### **Count I: Statutory Violations of Economic Sanctions Acts**

45. Congress has repeatedly insisted that humanitarian items in the form of agricultural products, medical devices, and drugs are sacrosanct - they are *not* to be interfered with by presidentially imposed economic sanctions. As is demonstrated below, each of the numerous statutory prohibitions placed on the president is absolute, explicit and direct. OFAC has violated at least three statutory provisions by its imposition of maximum pressure sanctions. Those violations are continuing today.

#### Count I(A): Violation of the International Emergency Economic Powers Act<sup>13</sup>

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<sup>12</sup> The letter was sent less than five months following OFAC's release of a new set of requirements foreign governments and financial institutions would have to adhere to in order to avoid secondary sanctions, *Financial Channels to Facilitate Humanitarian Trade with Iran and Related Due Diligence and Reporting Expectations* (October 25, 2019), available at [https://home.treasury.gov/system/files/126/iran\\_humanitarian\\_20191025.pdf](https://home.treasury.gov/system/files/126/iran_humanitarian_20191025.pdf).

<sup>13</sup> Title II of Pub. L. 95-223, *codified as* 50 U.S.C. § 1701 *et seq.*, commonly referred to as "IEEPA."

46. IEEPA is the wellspring of the president's sanctioning power. Specifically, Section 1702(a) of Title 50 lays out the president's powers. Those powers include, *inter alia*, the ability to "investigate, regulate, and prohibit" banking activities involving foreign countries, property transactions in which a foreign country or foreign national has an interest, and in times of hostilities exercise extraordinary powers.

47. Section 1702(b), "Exceptions to Grant of Authority," provides,

The authority granted to the President by this section does not include the authority to regulate or prohibit, directly or indirectly—

(1) . . . .

(2) donations, by persons subject to the jurisdiction of the United States, of articles, such as food, clothing, and medicine, intended to be used to relieve human suffering, [subject to terms and conditions not here germane].

Although it is not herein claimed that a specific U.S. person has donated either funds or articles for the relief of Iranian children suffering from epidermolysis bullosa or thalassemia, this statute clearly reflects a Congressional will that medical supplies and drugs are not to be intercepted or interdicted by either direct or indirect prohibition or regulation.

48. OFAC's imposition of maximum pressure sanctions in general, and in particular the requirements set forth in its October 25, 2019, Release promising exemption from possible secondary sanctions for foreign entities if those institutions agreed to comply with OFAC's requirements in order to avoid secondary sanctions, violate IEEPA because they illegally "regulate or prohibit, directly or directly," the transfer of "articles, such as . . . medicine, intended to be used to relieve human suffering."

Count I(B): Violation of the Trade Sanction Reform and Export Enhancement Act<sup>14</sup>

49. Plaintiffs reallege paragraphs 1 - 45, *supra*.

50. As noted above, IEEPA specifically restricts the President's power to "regulate or prohibit, directly or indirectly" humanitarian medical relief under certain conditions not here germane. In a noteworthy additional limitation on OFAC's authority in 2000, Congress further limited OFAC's ability to impose unilaterally sanctions upon agricultural or medical products and supplies. That statute, the Trade Sanctions Reform and Export Enhancement Act, provides in material part:

(a) New sanctions

Except as provided in sections 7203 and 7204 of this title and notwithstanding any other provision of law, the President may not impose a unilateral agricultural sanction or unilateral medical sanction against a foreign country or foreign entity, unless—

- (1) not later than 60 days before the sanction is proposed to be imposed, the President submits a report to Congress that—
  - (A) describes the activity proposed to be prohibited, restricted, or conditioned; and
  - (B) describes the actions by the foreign country or foreign entity that justify the sanction; and
- (2) there is enacted into law a joint resolution stating the approval of Congress for the report submitted under paragraph (1).

51. OFAC's unilateral reimposition of the previously terminated sanctions on Iran, followed by his unilateral imposition of the new maximum pressure sanctions, are illegal and void insofar as they prevented plaintiffs, "foreign entities" under the Act, from continuing to receive humanitarian aid. They are illegal and void because the reimposed and new sanctions were imposed unilaterally and the absence of Congressional authorization.

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<sup>14</sup> Pub. L. 106-387, *codified as* 22 U.S.C. Ch. 79, 22 U.S.C. § 7201 *et seq.*

Count I(C): Violation of Iran Financial Sector Sanctions<sup>15</sup>

52. Plaintiffs reallege paragraphs 1 - 45, *supra*.

53. Beginning in 2011, Congress authorized the President through OFAC to impose financial sanctions on Iran, including the Central Bank of Iran “or another Iranian financial institution designated by the Secretary of the Treasury for the imposition of sanctions pursuant to the [IEEPA].” 22 U.S.C. § 8513a(d)(1)(A). The following subsection, 8513a(d)(2), provides, “The President may not impose sanctions under paragraph (1) with respect to any person for conducting or facilitating a transaction for the sale of agricultural commodities, food, medicine, or medical devices to Iran.”

54. When OFAC on November 5, 2018, imposed new, unilateral financial sanctions on the over 70 Iranian-linked banks and financial institutions as SDNs, OFAC effectively froze the ability of those financial institutions, which constitute the bulk of Iranian financial entities, to participate in the sale and delivery humanitarian aid in violation of 22 U.S.C. § 8513a(d)(2).

**Count II - Negligence: Alien Tort Claim Act -  
Violation of OFAC’s Breach of Its Duty to Protect Iranian Children**

55. Plaintiffs reallege paragraphs 1 - 45, *supra*.

56. The preceding paragraphs starkly illustrate the impact that OFAC’s imposition of unilateral, maximum-pressure sanctions have on Iran. Today, thousands of Iranian children are suffering, and hundreds are dying, because of OFAC’s actions.

57. One of the primary purposes of the Alien Tort Claims Act was to protect the persons and property of aliens who are harmed by any tortious act by the United States and United States persons regardless of whether the aliens’ state is considered

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<sup>15</sup> Codified as 22 U.S.C. § 8513a.

an enemy, friend, or neutral in its relationship with the United States. It was created as a means of providing relief in United States courts to redress the injury caused by such torts. The Supreme Court recently indicated that the primary purpose of the Act was to promote “harmony in international relations by ensuring foreign plaintiffs a remedy for international-law violations in circumstances where the absence of such a remedy might provoke foreign nations to hold the United States accountable.” *Jesner v. Arab Bank, PLC*, 584 U.S. 218 (2018). Also, as the Supreme Court has recently articulated, the Act is intended to provide assurances to nationals of foreign countries, even those considered belligerent, of protection to the persons and properties and that America has a duty to assure those protections for certain classes of torts. See *Sosa v. Alvarez Machain et al.*, 542 U.S. 692 (2004).

58. OFAC’s duty toward Iranian children arises first from the text of the Alien Tort Claims Act, 28 U.S.C. 1350 (“ATCA”). That statute, passed in 1789 and one of the first laws of the United States, provides, “The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States.”

59. OFAC’s specific duty to protect Iranian children is reflected by the UN Convention on the Rights of the Child, or “UNCRC.”<sup>16</sup> The UNCRC is not a treaty of the United States because, although Clinton Administration’s UN Ambassador Madeleine Albright signed the convention on behalf of the United States on February 16, 1995, no president has ever submitted the convention to the Senate for ratification. Of all of the 193 member states of the United Nations, the United States is the only country that has yet to ratify the Convention.

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<sup>16</sup> UN General Assembly, *Convention on the Rights of the Child*, 20 November 1989,

60. In general, the term “law of nations” means “customary international law,” which in turn is defined as “international obligations arising from established international practices, as opposed to obligations arising from formal written conventions and treaties.”<sup>17</sup> The executive approval of the UNCRC by every member of the United Nations and its ratification by all member states except the United States establish that the UNCRC is indeed part of the customary international law, or the law of the nations.

61. The text of the UNCRC establishes the ways in which states - and, by extension, OFAC - are required to protect the rights of the child. It is critical to recognize that there are no territorial limitations on the application of the requirements quoted below:

- Article 3(2) requires states to “undertake to ensure the child such protection and care as is necessary for his or her well-being, taking into account the rights and duties of his or her parents, legal guardians, or other individuals legally responsible for him or her, and, to this end, shall take all appropriate legislative and administrative measures;”
- Article 6(2) requires states shall “ensure to the maximum extent possible the survival and development of the child;”
- Article 23, titled “Disabled Child,” in Paragraph (1), notes that states “recognize that a “mentally or physically disabled child should enjoy a full and decent life, in conditions which ensure dignity, promote self-reliance and facilitate the child;s active participation in the community;”
- Article 23(2) notes that states “recognize the right of the disabled child to special care and shall encourage and ensure the extension, subject to available resources, to the eligible child and those responsible for his or her care, of assistance for which application is made and which is appropriate to the child’s condition and to the circumstances of the parents or others caring for the child;”
- Article 24, titled “Health,” in Paragraph 1, notes that states “recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services;”

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United Nations, Treaty Series, vol. 1577, p. 3, available at <https://www.refworld.org/docid/3ae6b38f0.html>.

<sup>17</sup> [https://www.law.cornell.edu/wex/customary\\_international\\_law](https://www.law.cornell.edu/wex/customary_international_law).

- Article 24(2) requires states to “pursue full implementation of this right and, in particular, shall take appropriate measures –  
    “(a) To diminish infant and child mortality;  
    “(b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;  
    “(c) To combat disease and malnutrition, . . .”
- Article 24(4) requires states to “promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries.”

62. Following OFAC’s imposition of maximum pressure sanctions in November 2018, OFAC negligently failed to modify its new sanctioning packages to alleviate the intense suffering those new sanctions are today inflicting on Iranian children who suffer from thalassemia and EB.

63. Defendants have violated the legal requirements to protect plaintiffs as reflected in the following Articles of the UNCRC:

- Defendants violated plaintiffs’ rights as specified in Article 3(2) of the UNCRC by negligently failing to “ensure the child such protection and care as is necessary for his or her well being. . . .”
- Defendants violated plaintiffs’ rights as specified in Article 6(2) of the UNCRC by negligently failing to “ensure to the maximum extent possible the survival and development of the child.”
- Defendants violated plaintiffs’ rights as disabled children as specified in Article 23 of the UNCRC.
  - Defendants have violated plaintiffs’ rights to health care by negligently failing “to ensure that no child is deprived of his or her right of access to [the enjoyment of the highest attainable standard of health and

to facilities for the treatment of illness and rehabilitation of health].”

- Defendants have violated plaintiffs’ right to health care in the following specific particulars by negligently failing -

- (a) To diminish infant and child mortality;
- (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care; [and]
- (c) To combat disease and malnutrition, including within the framework of primary health care, . . . .

In sum, Defendants have violated their duty to protect the life and health of plaintiffs through their negligent maladministration of the unilateral maximum pressure sanctions which prevents the international sale and transport of life-saving medical supplies.

## **VI. Prayer for Relief**

64. WHEREFORE, plaintiffs herein request the court to grant them the following relief:

Declaratory Judgment: A declaratory judgment that:

- The current Iran sanctions regime is illegal and unenforceable because it failed to comply with the requirement of Congressional prohibitions on economic sanctions contained in the International Emergency Economic Powers Act, the Trade Sanctions Reform and Export Enhancement Act, and the Iranian financial sector sanctions legislation;
- OFAC is bound by customary international law to comply with the provisions of the UNCRC and provide protection and relief to Iranian children who are physically suffering because of the imposition of OFAC’s “maximum pressure” sanctions;
- The current Iran sanctions regime does not authorize the imposition of



economic sanctions on any entity that provides or assists in the provision of humanitarian aid to Iran.

Injunction:

- An injunction prohibiting OFAC from enforcing sanctions against any entity that provides or assists in the provision of humanitarian aid to Iran,

or, in the alternative,

- An injunction prohibiting OFAC from enforcing sanctions against any entity that provides or assists in the provision of medical devices and drugs to treat the diseases of epidermolysis bullosa and thalassemia.

Attorney Fees: Plaintiffs' attorney fees and costs under the provisions of the Equal Access to Justice Act, 5 U.S.C. § 504.

DATED this 15th day of August, 2022, in Zigzag, Oregon.

/s/

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